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Italy

Food and Agricultural Import Regulations and Standards

Country Report

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Report Highlights:
Report contains food and agricultural import regulations for Italy. This report supplements GAIN Report E23195 on EU labeling requirements, trade regulations customs and standards. Policies and regulations are flexible, and are subject to change. Exporters are encouraged to work with Italian importers to ensure streamlining of labeling, distribution and import approval.

Includes PSD Changes: No
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DISCLAIMER: This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in Rome, Italy, for U.S. exporters of domestic food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. FINAL IMPORTANT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY`S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

SECTION I. FOOD LAWS

The Italian food sector follows European Union rules and regulations with the exception of those products for which there are no EU rules and regulations. Apart from these exceptions any product manufactured in any EU-member country in accordance with that country's rules and regulations can freely circulate in all other EU countries, even if different standards apply in the other country. The same is true of an imported product, if it enters one EU country it can be transshipped to Italy without further inspection as long as its label is in Italian and if the product does not present a risk to human or animal health. (Please see the Labeling portion of this report for more information.)

Italian authorities implement EU rules (directives and decisions) for food and agriculture through the country specific laws and decrees. However, there are still a number of issues where EU and Italian rules are not yet harmonized. In this event, the rules are issued by country laws and decrees. Food Safety is the primary responsibility of the Ministry of Health. Food production is the primary responsibility of the Ministry of Agriculture. In some instances other Italian Ministries are involved, including; Ministry for Productive Activities (standards, labeling and trade promotion), and the Ministry of Economy and Finance (customs and duties).

On December 13, 2003, the European Council selected Parma, Italy as the European Food Safety Authority's permanent location. The Italian government is in the process of designing a National Food Safety Authority, but no final decision has yet been made.

U.S. food and beverage products require no special permits nor are they subject to special rules or regulations regarding their retail sale in Italy. The products must comply with rules and regulations as would any other product sold in the EU market. US exporters should also be aware that any food or agricultural product transshipped through Italian territory must meet Italian requirements, even if the product is transported in a sealed and bonded container and is not expected to enter Italian commerce.

Two exceptions to EU rules and regulations pertain to specific additive restrictions and limitations (including coloring and modified starches). Moreover, products that could be dangerous for public health (i.e. unbalanced dietary products) are not permitted for sale. In these cases it is necessary to comply with Italian regulations.

Health certificates are required for certain specified products such as canned and/or frozen fish products, meat and meat based products, milk, pasteurized cream, mollusks and wines (certificate of analysis).

Import permits are required only for certain products as set forth by EC/EU regulations such as mineral water, meat based products, canned mushrooms, mollusks, and frozen foods. Request for import permits must be filed with the Ministry of Foreign Trade. (See Annex A)

In Italy, the supervision on the application of the regulations (often EU sources) relatively to food and nutrition, in general, is assigned to the Ministry of Health and to its central and local offices. These regulations, especially sanitary laws, are strictly enforced.

SECTION II. LABELING REQUIREMENTS

A. General Requirements

Food labeling and ingredient regulations have been harmonized within the EU for most part. Italy sets its own national requirements where EU standards are not yet established. Some of these standards hamper imports of beef, game meat, processed meat products, diary products, frozen foods, seafood, citrus, alcoholic beverages, snack foods and confectionery products.

The two main Regulations with respect to labeling are the Council regulation 2000/104/EC and the Council Directive 2000/13/EC + CORRIGENDUM (English version of Annex III). Italian labeling and ingredient legislation is based on EU rules and regulations. Nevertheless, Italy maintains specific labeling and ingredient rules for some food products. U.S. food products can generally be uniformly packaged for sale in all EU Member States based on the condition that they conform to the national law set forth in at least one member state. Italy also requires that labels be in the Italian language. Many international companies provide multi-language labels to ensure the possibility of sale throughout the European Union.

In Italy there are two laws that regulate food product labeling, both of which implement EU directives: one decree concerns the mandatory specifications (Legal Decree 2003/181 putting into effect the directive 13/2000/EC, provides guidance on the detailed information that must be displayed on labels, the presentation requirements and allowed exceptions) and the other concerns nutritional labeling specifications.

The standard U.S. label fails to comply with Italian rules and regulations. A sticker with the translation of the U.S. label and with all the mandatory information listed below should be placed on the packaging above or in addition to the U.S. label when the product is sold in Italy.

All food and beverage products imported into Italy for retail sale must provide the following information:

a. Name of the product as commonly used in the trade
   The name established by the law or, if this is lacking, a brief description of the product.
b. List of ingredients and food additives in descending order by weight
   The following ingredients require a specific statement on the label: GMOs, packaging gases, sweeteners, aspartame, polyoils, quinine and caffeine.
c. Quantitative ingredient declaration (QUID)
   The quantity of certain ingredients or categories of ingredients is mandatory in the following cases:

- Where the ingredient or category of ingredients appears in the name under which the foodstuff is sold
- Where the ingredients or category of ingredients is usually associated with that name by the consumer
- Where the ingredient or category of ingredients is emphasized on the labeling in words, pictures or graphics
- Where the ingredient or category of ingredients is essential to characterize a foodstuff and to distinguish it from similar products

d. Metric units for all measurements
The nominal net content or weight expressed in metric units: (weight in grams, liters, kilograms, centiliters, etc.). A small "e" on the label may be used to guarantee that the actual content corresponds to the quantity indicated.

e. Expiration date
Every package must have listed the minimum shelf-life period. Preferred language is: "To be consumed preferably by DD/MM/YY". It is also possible to state the time limit of consumption if the food is stored and prepared properly.

f. Storage conditions
Any special storage conditions or conditions of use should be stated. Instructions for use should be given as necessary.

g. Alcoholic content
This is required for drinks with alcoholic content equal or greater than 1.2 per cent in volume.

h. Name or business name and address of manufacturer, packager, vendor, importer established within the European Union

j. Country of origin
Particulars of the place of origin or provenance in case absence of such information might mislead the consumer.

k. Lot Marking
Council Directive 89/396/EEC requires that foodstuffs carry a mark identifying the lot to which a foodstuff belongs.

l. Instructions for intended use
If necessary

m. Treatments undergone, with specific indications for irradiate (see Section VII Paragraph J) or deep-frozen foods (see Section VII Paragraph H)

The www.useu.be/agri/usda.html website provides a broad range of useful information on EU import rules and food laws and allows easy access to USEU reports, trade information and other practical information. More information on EU labeling rules can be found at www.useu.be/agri/label.html.

B. Medical/Health Claims

Nutritional Value Labeling Ordinance

Nutritional labeling is not mandatory in Italy and other EU countries unless there is a special mention of the nutritional content or benefits on the label itself or in advertisements for product. The presence of a U.S. nutritional label (Nutrition Facts) may be considered to be equivalent to a nutritional claim and consequently its presence on the label requires to draw up the nutritional table according to Italian and European standards as well. To avoid this problem, many U.S. products place their Italian label over the portion of the U.S. label containing nutritional information.

Where nutrition labeling is provided, the information to be given should consist of either group 1 or group 2 in the following order:

Group 1
- ✧ The energy value
- ✧ The amount of protein, carbohydrate and fat

Group 2
- ✧ The energy value
- ✧ The amount of protein, carbohydrate, sugar, fat, saturates, fiber and sodium

The energy value and the proportion of nutrients must be declared in specific units per 100 grams or per 100 milliliters. Information on vitamins and minerals must be expressed as a percentage of the recommended daily allowance (RDA).

The information on the label must be presented in tabular form with the numbers aligned or if space does not permit, in linear form in a language easily understood by the purchaser.

The nutritional labeling rules are laid down in Legal Decree n. 77 dated 16/02/1993, putting into effect the Council Directive 90/496/EEC.

Health Claims

Medical claims that expressly or implicitly affirm or suggest that a food product has a healing (curative) or preventive effect are prohibited in the Italian/EU labeling directive. Only rather bland references that the product has general beneficial effects are allowed as long as these are not misleading to consumers. U.S. exporters of "health" foods, weight loss/diet foods, baby foods and vitamins should work closely with an Italian importer, since Italian labeling laws regarding health claims can be particularly stringent. Italian legislation sets forth orders, obligations and criminal sanctions for violations.

Dietetic Foods Ordinance

With the Decree dated April 23rd 2001, that modifies the Annex I of the Legal Decree n. 111 dated January 27th 1992, the Italian Ministry of Health establishes all food products destined to particular nutrition habits that will be subject to specific ministerial decrees such as:

1) Products for newborn babies and products for weaning;
2) Cereal products and those products for newborn babies;
3) Low fat products for weight loss diets;
4) Low fat products for specific medical purposes;
5) Products for athletes and those who practice intensive sports;

Specific regulations can also be made for those products for people who suffer from diabetes.

On May 21, 2004, Italy adopted Council Directive 2002/46/CE relating to the application of labels for those products that contain plants which have been recognized as dietary supplements for "physiological" effects. In addition, a review of those products that contain "herbalist" ingredients has been in progress for several years, according to Circular n. 3 dated July 18th 2002.

New Allergen Labeling

On September 29 2003, the Council and the European Parliament adopted an important amendment to the EU's general food labeling directive (Directive 2000/13/EC). Listing all sub-ingredients of compound ingredients on the label will become mandatory thus enabling consumers to identify any allergenic ingredients.

SECTION III. PACKAGING AND CONTAINER REQUIREMENTS

A. Consumer Packaging Ordinance and Laws on Weight and Measures

Council Directive 76/211/EEC (amended by Commission Directive 78/891/EEC) specifies the maximum tolerable error between the actual content and the quantity indicated on the label of prepackaged products.

B. Materials in Contact with Foodstuffs

Regulations for materials in contact with food have been EU-harmonized (see www.useu.be/agri/packaging.html). In Italy, by means of Decree n. 267 dated May 30th 2001, containing the updated regulations of the Ministerial Decree dated March 21st 1973, the Ministry of Health established the sanitary discipline for packages, containers, recipients and tools that can come in contact with food products and products for personal use.

C. Packaging Disposal Regulations

In Italy, issues concerning the production, recycling and disposal of packaging materials and waste are governed by articles 34 to 43 of the Ronchi Decree, Legal Decree n. 22/97, putting into force the Council Directive 94/62/EC. The provisions contained in these articles apply to a broad range of packaging issues, including prime materials utilized for packaging, finished packaging for retail/unit sales of products and for wholesale or warehousing use (multiple or secondary packaging), packaging for transportation, waste or by-products from packaging, management of packaging waste, and the reuse, recycling and disposal of packaging, its waste or by-products.

The principal scope of the Ronchi Decree is to encourage the reuse and recycling of packaging. To this end, article 37 of the Ronchi Decree sets forth certain objectives which must be met by producers and users of packaging during a period of five years from the date of effectiveness of the provisions relative to packaging (i.e., by 1 May 2002). These objectives are listed in Attachment E to the Ronchi Decree as follows:

	Minimum	Maximum
a) Packaging waste to be reused as material or components for energy: by weight at least	50%	65%
b) Packaging waste to be recycled: by weight at least	25%	45%
c) Any packaging material to be recycled: by weight at least	15%	15%

Producers and users of packaging may perform their obligations for reuse, recycling and collection by one of the following means:

- ✓ organizing independently the collection, reuse, recycling and recuperation of packaging waste;
- ✓ join the National Packaging Consortium (described below);
- ✓ establish a return system to repurchase used packaging.

National Packaging Consortium - CONAI (Consorzio Nazionale Imballaggi) is responsible primarily for the preparation of a general packaging waste management and recycling program (the "General Program") that designs to meet the reuse and recycling objectives listed in article 37 and Attachment E to the Ronchi Decree (please refer to table above).

The web site of the *European Food Service and Packaging Association*: www.efpa.com/laws.html provides information on EU packaging directives and food laws.

D. Phytosanitary Inspection on USA Packaging

The EU has taken measures necessary to stop the potential infestation of destructive pine wood nematodes (PWN), implementing emergency measures restricting imports of wooden packaging materials originating from Canada, China, Japan and the U.S. if not heat, pressure or chemically treated (Commission Decision 2001/219/EC which is an extension of Council Directive 2000/29/EC).

In Italy the Commission Decision has been put into effect by the Ministry of Agriculture through the Decree n. 273 dated August 21st 2001. Wood products can be introduced onto the national territory only with an authorization of the regional phytosanitary service, subordinate to the presence of a declaration or a trade-mark that certifies that the treatment has been made. The Phytosanitary Regional Service will issue the authorization for imports after certifying the presence of a label on the packaging that identifies who has made the phytosanitary treatment and where, with the possibility to make further examinations.

SECTION IV. FOOD ADDITIVE REGULATIONS

A. Food Additives and Flavourings

Food additives have been already fully harmonized within the EU (see www.useu.be/agri/additive.html). The Italian food additive sector is governed by the EU directive 72/98/EC adopted by Ministry of Health Ministerial Decree n. 209 dated February 27, 1996, and updated with the Decree n. 183 dated March, 10, 2000. This directive covers all food additives including coloring, additives and sweeteners. There are positive lists for additives, colorings and sweeteners that can freely be used in all food products, except for certain product categories, and there are also some specific lists of preservatives, antioxidant and other additives which have a limited use in certain food products.

Additives should be listed on labels by indicating first the specific function they perform (preservative, color, sweetener, emulsifier, etc.) and then specifying the name of the additive (i.e. sorbic acid) or the EEC classification number (i.e. E 200).

The use of sweeteners must also be mentioned with the name of the product, i.e., “with sweetener(s)” and warnings must also be made such as “Excessive consumption may have laxative effects for products with a polyol content in excess of 10%” or “contains a phenylalanine source” for products with aspartame.

The use of inert gas to extend shelf life of products is not considered an additive therefore there is no obligation to indicate the addition of gases. The label must, however, show the message: "Packaged under protective atmosphere". As a general rule the additives accepted by the Codex Alimentarius match the additives allowed in the European and Italian regulation.

The Ministry of Health regulates the quantity of aromas destined to food products through the Legal Decree n. 107 dated January 25th 1992 and its updated version, Decree n. 100 dated March 5th 2003.

B. Vitamin-Enriched Foods

The use of vitamins is still awaiting EU harmonization. At the moment Member States have very different rules on adding nutrients to foods. In Italy, the Legal Decree n. 31 dated February 14th 2003, that puts info effect the directive 2001/15/EC, establishes the substances that can be added to specific products for nutritional purposes.

SECTION V. PESTICIDES AND OTHER CONTAMINANTS

A first step to harmonize EU legislation on pesticides was made by the introduction of Council Directive 76/895/EC establishing the maximum residue levels in order to guarantee free movement throughout the member states. In Italy, the type and maximum quantities of pesticide residues that may be legally present in food products are regulated by art. 5 of the 283/62 decree (general hygiene regulations). All pesticides listed on the positive list are permitted and decrees for their use are issued and updated by the Italian Ministry of Health.

The reference law for MRLs is outlined by the Minister of Health Decree dated 19 May 2000 (Decreto del Ministro della Sanità del 19 maggio 2000), which establishes MRLs pertaining to foodstuff for human consumption. It implements EU Directives 97/41/CE and 1999/65/CE and 1999/71/CE. The Decree has been updated fourteen times, with the last update dating February 19, 2004. It includes MRLs that are set by implementation of EU Directives as well as those that are set at country level. We expect an update to this decree from the Italian Ministry of Health sometime in 2004. For more information on MRLs, please refer to FAS/Rome report IT4012.

A consolidated text of the Italian law with all the annexes and the updates on MRLs is available (in Italian) at:
http://www.ministerosalute.it/alimenti/sicurezza/sicApprofondimento.jsp?lang=italiano&label=pro&id=167

Specific decrees set forth a list of extraction solvents allowed in the production of foodstuffs and food ingredients, along with their prescribed usage and maximum residue tolerances (Legal Decree February 4, 1993 no. 64, putting into force the Directive 344/88/EEC and Ministerial Decree 557/94). This Decree has been modified to comply with EU rules.

For more information please visit: www.useu.be/agri/pesticides.html

SECTION VI. OTHER REGULATIONS AND REQUIREMENTS

A. Product Inspection and Registration

Member States are responsible for carrying out inspections on a regular basis and ad-hoc in cases where non-compliance is suspected. Products can be checked at import or at all further

stages of marketing. In case of non-compliance, the EU hygiene directive (Com. Reg. 93/43/EEC) allows the Commission to suspend imports from third countries or introduce special conditions for products from the third country concerned, applicable on the entire EU territory.

The criteria for laboratories conducting food controls have been harmonized but it is the Member States' responsibility to designate laboratories allowed to perform analyses (Council Directives 89/397/EEC and 93/99/EEC). Specific detailed inspection requirements exist for animal products. Inspections are carried out under the supervision of a veterinarian at a limited list of ports and border inspection posts (BIP`s – Border Inspection Post. In Italy called P.I.F. Posti d`Ispezione Frontaliera)

Fresh fruits and vegetables are subject to phytosanitary controls and are checked for compliance with EU-harmonized marketing standards, controlled by Italian Inspection Post, controlled by the Ministry of Health (USMA- Uffici di Sanita` Marittima, Aerea e di Confine) Details about the conformity checks are laid down in the EU regulation 1148/2001. These have been established for apples and pears, apricots, artichokes, asparagus, aubergines (eggplant), avocados, beans, Brussels sprouts, cabbage, carrots, lettuce, curly and escarole chicory, melons, onions, peaches and nectarines, peas for shelling, plums, spinach, strawberries, sweet peppers, table grapes, tomatoes, watermelons, witloof chicory, for miniature produce, walnuts and hazelnuts.

Marketing standards for fruit and vegetables can be downloaded from www.useu.be/agri/Fruit-Veg.html.

Inspection fees differ from one Member State to another. Measures in case of non-compliance also vary widely, ranging from non-admittance of a product to forced destruction. This may be a decisive factor in choosing a port of entry for products where problems are more likely.

Generally, there is no EU requirement to register imported foods except for the introduction of novel foods (see Section VII-C). The person/company introducing a novel food has to submit a request to the authorities in the Member States where the product will be marketed and a copy of this request has to be sent to the Commission's Health and Consumer Protection Directorate.

Importers of organic products (see section VII- I) are required to notify the competent regulatory authority of the Member State of their activity. The introduction of foodstuffs with particular nutritional uses needs to be notified to the Member State where the food is sold. Exporters of vitamin-enriched foods or nutritional supplements are especially advised to check for the existence of specific Member State registration or notification requirements.

The Council Directive 89/397/EC was put into effect through the Legal Decree n. 123 dated March 3rd 1993 regulating the official inspection activities on food products that must be made within the EU.

Processing plants producing meat and meat products, dairy, fish and egg base products must register and comply with the good manufacturing practices in processing, packing and storing human food. Legal Decree 155/97, putting into force 43/93/EEC, requires that all manufacturing plants adopt the HACCP method. Consequently all foreign processing plants need to have a certification system and methods equivalent to the EU regulations.

Meat, milk, fish and egg-base products must be accompanied by specific veterinarian and test certificates.

Product samples must comply with the food regulations applicable in the EU. Food samples can benefit from tax exemptions but must undergo all hygiene or labeling requirements. Health certificates accompanying food products are issued by the health or veterinary authorities of the exporting country.

B. Certification and Documentation Requirements

AGRIM Certificates

The EU requires import licenses (AGRIM certificates) for most agricultural products for which it provides market support, including grains, milk, meat, olive oil, most fruits and vegetables, wine and sugar. In order to obtain a license, an application form must be submitted and security fee must be paid to the issuing Member State. Licenses vary in validity with most expiring three months after the month of issuance.

Health Certificates

- Plant Products

www.useu.be/agri/plantcertif.html
Phytosanitary certificates issued by APHIS must accompany fruit, vegetable and nut shipments to the EU.

- Animal Products

www.useu.be/agri/certification.html
The European Community is in the process of harmonizing legislation on imports of animal products. This is a three-stage process that starts with the recognition of a country to export a certain animal product. The U.S. is recognized by the EU for nearly all animal products.

Directive 97/78/EC, as amended, lays down principles for veterinary check on products imported from third countries. Inspections of consignments include: documentary check (health certificates), identity check (visual inspection to ensure consistency between certificates and product) and physical check (inspection of the product itself). Directive 2002/99/EC establishes animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption.

In a second stage, lists of EU approved establishments are drawn up in recognized countries. Various U.S. agencies, including FSIS, APHIS, AMS, and FDA are involved in the listing process. Establishments are subject to EU inspections prior to listing and/or to occasional EU audits after listing. Exporters should be aware that getting a plant listed can take several months. Lists of products that must come from an EU-approved establishment can be accessed through www.useu.be/agri/estab.html

The third level is the requirement that all shipments be accompanied by animal health and/or public health certificates signed by U.S. officials to guarantee that individual lots or shipments of products meet EU requirements.

The EU has not yet completed harmonization of import requirements for other products.
In these cases import regulations are still under the control of the individual Member States. This often results in the 25 Member States maintaining different sets of lists of third countries, lists of establishments, certificate requirements, and inspection programs.

A general guidance for third country authorities on the procedures to be followed when importing live animals and animal products into the European Union can be downloaded from: http://europa.eu.int/comm/food/international/trade/guide_thirdcountries_en.pdf

- Processed Foods:

All animal products imported into the EU need animal or public health certification. For processed foods containing animal product, the situation is more complicated because there is no legislation specifying the percentage of dairy, egg, red meat or poultry meat that a foodstuff must contain to necessitate certification. However, the specific EU legislation applicable to the animal product in question contains certain provisions on certification. For more information, please refer to www.useu.be/agri/foodcertif.html

Directive 2001/101/EC adds meat as a category and provides at the same time a strict definition for the term meat. Commission Directive 2001/101/EC, effective since January 1, 2003 harmonizes the definition of meat at EU level. The new rules apply to products that contain meat as an ingredient, while meat sold without further processing is excluded. Detailed information on imports from third countries of products of animal origin, including specific provisions for different meats can be found at: http://www.europa.eu.int/scadplus/leg/en/s84000.htm

- Red meat & poultry meat:

Products containing any amount of red meat or poultry meat must be certified.

- Egg products & dairy:

Certification of products containing egg products or dairy products depends on the composition of the product in relation to the definitions in the relevant Community legislation.

As a rough guideline, if foodstuffs contain more than 50 percent egg products/dairy products, the Commission believes they should be considered as such. More details are available from the above shown web site. Further, the competent authorities of the importing EU Member State should be contacted for their interpretation of the Commission's guidelines.

Although there are no harmonized EU certificates for processed foods such as canned vegetables, soup broth, etc., EU Member States often require that shipments be accompanied by a certificate signed by U.S. officials. Exporters should check with their importer or with the Office of Agricultural Affairs in Rome determine which documentation is required.

More information on EU import requirements for animal products is available at: www.useu.be/agri/certification.html.

SECTION VII. OTHER SPECIFIC STANDARDS

A. Genetically Modified Food and Feed

In April 2004, the EU's new regulation for labeling biotech derived food and feed products and for implementing a traceability system identifying what kind of biotech events have been used in the production of food/feed products. The key outcomes that apply to U.S. exports are that all food/feed, including processed products, produced from biotech goods must be labeled, (including products that no longer contain detectable traces of biotech). The allowable adventitious presence (AP) level for EU-approved biotech varieties for use in food,

feed and processed products is set at 0.9 percent (above this AP level, products must be labeled).

Italy has not yet established an implementation plan for these new regulations. However, biotech food, feed, and planting seeds have been banned from Italy since August 2000 by the Amato Ministerial Decree. To date, no products sold in Italy are known to be labeled as containing biotech ingredients.

Please see EU GAIN report E23197 for biotech labeling requirements.

B. Novel Foods

The Novel Food Regulation 258/97 lays down detailed rules for the authorization of novel foods and novel food ingredients, including foods derived from or containing or consisting of products derived through modern agriculture biotechnology. For more information, please refer to www.useu.be/agri/novelfood.html

Novel foods and feeds are not the only products derived from GMOs. This term also applies to food and feed products actually new to the EU market. These can be exotic fruits and juices which have not to a significant extent been marketed in Europe. The EU novel food regulation requires an evaluation process for these novelties including a risk assessment process. Just recently, non-juice and a DHA rich oil extracted from aldae schizochytrium sp. received EU approval.

C. Functional Foods – Food Supplements

The Directive of European Parliament and of the Council 2002/46/EC of June 2002 on the approximation of the laws of Member States relating to food supplements establishes harmonized rules for the labeling of food supplements and introduces specific rules on vitamins and minerals in food supplements. The aim is to harmonize the legislation and to ensure that these products are safe and appropriately labeled so that consumers can make informed choices.

D. Animal Products

Meat and poultry (including game and fowl) products can only be imported from U.S. plants approved by the European Union (EU). All meat products (beef, pork, veal, lamb, etc.) in any form (including canned, frozen, soups, stews, etc.) must also be accompanied by the following certificates issued at the slaughtering or processing plant by a U.S. Department of Agriculture meat and poultry inspector.

FSIS Form 9060-5	Meat and Poultry Export Certificate of Wholesomeness
MP 150	Animal Health Certificate
MP 157	Public Health Certificate
MP 410-10	Beef and Other Meats
MP 410-11	For Processed Meats Only
MP 410-12	For Pork Products Only
MP 410-13	Domestic Ruminants *Hormone-Free Certification

All poultry products (chicken, turkey, duck, quail, etc.) must be accompanied by the following products:

FSIS Form 9060-5	Meat and Poultry Export Certificate of Wholesomeness
MP 70	Sanitary Certificate
MP 58	Fresh Poultry
MP 59	Processed Poultry Products

E. Animal By-Products

In October 2002, the European Commission approved legislation (Regulation 1774/2002) that requires animal by-products not intended for human consumption, including blood products, hides and pet food, be derived from the carcasses of animals fit for human consumption. The legislation prohibits the use of any rendered protein which was obtained from animal carcasses that were unfit for human consumption as an animal feed ingredient or for pet food.

The proposed legislation was initially developed in response to the Bovine Spongiform Encephalopathy (BSE) crisis but has been broadened to address several animal and public health issues. The Animal By-Products regulation replaced Directive 90/667/EEC on the disposal and processing of animal waste and amended Directive 90/425/EEC.

As for Catering Waste (including yellow grease):
A four-year derogation allows Member States to keep incorporating certain types of catering waste into feed. However, given the ban on intra species recycling, no catering waste containing swine products, for instance, can be used in swine feed.

F. Beef Labeling

The EC Regulation n.1760/2000 of the European Parliament and Council of July 17th 2000 establishes the obligation of specific labeling for beef and products made with beef, in order to allow traceability and provide clear information to final consumers.

A compulsory beef-labeling scheme has been in place since September 2000. Full implementation of the beef-labeling scheme went into effect on January 1st, 2002. Under this scheme, labels for all bovine meat must indicate the following information:

- "Born in: third country"
- "Reared in: third country or third countries". The above can be combined if the animal was born, raised and slaughtered in the same third country, i.e. "Origin: third country"
- "Slaughtered in: third country / approval number of slaughterhouse"
- "Cutting in : third country / approval number of cutting plant"
- A traceability code linking the meat to the animal or a group of animals representing the production of maximum one day.

The EC 1760/00 regulation is applied in Italy under the Ministerial decree 22601 dated August 30th, 2000 and its revision 1 dated May 31st, 2001.

G. Egg Labeling

The mandatory marking of grade A eggs (fresh eggs for human consumption) by a code designating the producer and farming method enters into force on January 1, 2004. Each egg produced in the EU must be individually stamped with one of the following codes

indicating the farming method: O = organic, 1 = free range, 2 = barn, 3 = cage. For eggs imported from the U.S., the new rules are not totally clear yet. The European Commission must first evaluate the U.S. labeling rules in force to determine whether they are equivalent to the EU's technical rules and standards. Pending the outcome of this evaluation, imported grade A eggs may be stamped individually with either a code corresponding to the mentioned methods of production or with a code identifying the unspecified nature of the farming method.

For more information see www.useu.be/agri/label.html

H. Olive Oil Labeling

An EC regulation (applicable from November 1st 2003) provides guidance for the new definitions on the labels and the regulations of the different mixtures.

Olive oil must be sold in containers that have a capacity of maximum five liters, with a breakable seal and an adequate labeling indicating the different categories of olive oil.

The new classification of olive oil includes four categories: "extra virgin olive oil ", "virgin olive oil", "olive oil composed of refined olive oil and virgin olive oil" and "olive pomace oil" (which is made from olive residues).

The new regulation does not allow to indicate the presence of olive oil on the label in case of those oils mixed with other vegetable oils, unless olive oil represents at least 50% of the mixture. It is also necessary to indicate the percentage of olive oil on the total weight of the product or the percentage on the total fat contained in the product.

It is not mandatory to state the origin of the olive oil on the label. It is possible, and might be verified, to provide the following statements: "first cold pressing" and "cold extract".

The general regulations regarding labeling and the necessary indications for olive oil are listed in the Legal Decree 109/92.

I. Pet Food

All pet food imported from the U.S. into the European Union must meet EU requirements, relating mainly to health and labeling aspects. The web site www.useu.be/agri/petfood.html provides a broad range of useful information on EU import rules and pet food laws and allows easy access to USEU reports, trade information and other practical information.

The Italian Ministry of Health maintains two separate lists of U.S. pet food manufacturing facilities that are authorized for export to Italy. The first lists facilities which produce finished pet food products and the other lists facilities that produce animal proteins/pet food ingredients. These lists are currently under revision by APHIS following approval of facilities for compliance with EU Regulation 1774/2002.

J. Seafood Products

Seafood products from the U.S. must be accompanied by a health certificate (using the model prepared according to Commission Decision 2001/67/EC for fishery products and Commission Decision 96/333/EC for mollusks, echinoderms, tunicates and marine gastropods), issued either by the Food and Drug Administration or by the National Marine Fisheries Service.

Commission regulation (EC) number 466/2001 sets maximum levels for certain contaminants in food, including maximum levels for lead in crustaceans excluding brown crabmeat. This level was set at 0.5 mg per kilogram.

Since January 1, 2002, the Commission Regulation 2001/2065/EC imposed new requirements for the labeling of fishery and aquaculture products intended to the retail sector, which must now include the following information:

a) The Commercial name of the species
b) The production method (aquaculture or fishery product). The proper language to use is "caught in." "caught in fresh water", "farmed" or "cultivated".
c) The catch area. Products caught at sea have to show the area of capture (taken from the FAO list, Annex of the above Regulation - only the general area has to be mentioned and not the Area codes). Products caught in fresh water require a reference to the Member State or third country of origin of these products. As for farmed products, the reference is to the Member State or third country in which the product undergoes the final stage of development.

K. Fruits and Vegetables

A U.S. Department of Agriculture phytosanitary certificate must accompany fresh fruits and vegetables and unprocessed/raw nuts or PPQ577 issued by an official USDA Animal, Plant Health Inspection Service (APHIS) inspector. The certificate is issued upon inspection of the exported commodity to determine that it is free of insects, plant diseases, and other organisms considered harmful by the receiving country. Inspections are arranged through written application filed at the nearest APHIS office. For more information contact USDA/APHIS PPQ (Plant Protection and Quarantine), 4700 River Road, Unit 140, Riverdale, MD 20737. Tel: (301) 734-8537. Fax: (301) 734-5786.

The Legal Decree n. 306 dated December 10th 2002 (G.U n.25 del 31/01/2003) in force since February 15th 2003 states that without or with an incorrect label on fruit and vegetable products the producer risks to pay a fine between €550 to €15,500 (about $685-$18,200).

L. Frozen Foodstuffs

Council Directive 89/108/EEC lays down rules for quick-freezing foodstuffs and for their packaging and labeling (it does not cover ice creams and other edible ices). These rules apply to all quick-frozen foodstuffs intended for supply without further processing to the final consumer and to foodstuffs that need further processing or preparing. In addition to the requirements indicated in the above, the following indications must be included in the labeling of foodstuffs intended for supply without further processing to the final consumer, restaurants, hospitals, canteens or other similar mass caterers:

✓ The sales name with the indication "quick-frozen" and the date of minimum durability, the period during which the purchaser may store the product, the storage temperature and/or type of storage equipment required
✓ Batch identification and a clear indication of the type "do not refreeze after defrosting"
✓ The labeling of quick-frozen products that need further processing must include only the following indications (on the packaging, container or wrapping or on a label attached thereto):
✓ The sales name with the indication "quick-frozen"
✓ The net quantity
✓ Batch identification
✓ The identity of the packer, manufacturer or of seller

In Italy, the production, commercialization and sales of frozen food destined to human nutrition and import from non-EU countries is regulated by specific dispositions:
- Legal Decree n. 110 dated January 27th 1992 implements the above mentioned Council Directive 89/108/EEC
- Ministerial Circular n. 21 dated April 27th 1992
- Ministerial Decree n. 493 dated September 25th 1995 implements the Directive 92/1/CEE relative to temperature control of frozen foods and 92/2/CEE relative to sampling and analysis methods for temperature control.

M. Organic Food

The basic regulation covering the production, labeling and imports of organic foods in the European Union is Council regulation No. 2092/91 and 1935/95. The U.S. organic food production and certification system has not yet been judged equivalent to the Italian certification system. Thus, imported U.S. organic products need to be certified by a U.S. certifying entity and the Italian importer needs to request a special import permit.

Products with more than 95% organic ingredients are considered to be fully organic. Products with more than 70% of organic ingredients may only mention this in the list of ingredients. Other products must avoid the term "organic". Health products are subject to the same regulations that apply to other food products.

In the Circular 3/2000 dated June 16th 2000, published on the "Gazzetta Ufficiale" of October 2nd 2000, the Ministry of Agriculture has established the procedural course for the import of organic products from other countries, as well as the regulations for those operators that buy organic products from a foreign country and import them on national territory.

The procedure starts when the notification of importation is sent to the Ministry of Agriculture while a copy is sent also to the Examination Institution that operates throughout the national territory. This institution will then start the procedure for the verification of the conditions when entering the country. When completed, the Institution will send the certificate of approval (or it might not) to the Ministry of Agriculture for the importer to enter the system. In case of a positive result, the Ministry will communicate to the company and the Examination Institution the registration in the importer's list of organic products. Import operations can start when the company has received the communication of registration in the national importer's list of organic products from the Ministry of Agriculture.

For those imports which are not listed in the list subject to the EC regulation n. 94/92 and to its following modifications (EC regulation n. 2092/91, art. 11 paragraph 1 – 5), the operator will have to proceed as described above as well as prepare further documentation.

For more information visit the web site: www.useu/be/agri/organic.html

N. Irradiated Foodstuffs

Harmonization of EU rules on food irradiation is still at an initial stage and U.S. exporters of irradiated foodstuffs should check individual EU Member State legislation for compliance.

In Italy, the Legal Decree n. 94 dated January 30th 2001, that puts into effect the directives 1999/2/EC and 1999/2/EC, disciplines the production, commercialization and import of

irradiate products. The above mentioned decree is not applied to those products prepared for patients receiving medical care who are in need of sterilized product, even though it is prohibited to add radioactive substances to food products. In case of those products exposed to ionized radiation, it depends on the quantity absorbed.

For more information visit the web site: www.useu.be/agri/irradiation.html

O. Beverages

EU regulations govern beverages such as wine, beer and other alcoholic beverages. They determine both production methods and labeling requirements. Great importance is given to safeguarding the controlled appelation of origin for wine, DOC.

The www.useu.be/agri/wine.html website provides a broad range of useful information on EU import rules and beverage laws.

P. Quinine and Caffeine

Commission Directive 2002/67/EC, scheduled to come into force by July 2004, requires the compulsory labeling of quinine and caffeine when they have been used in the production or preparation of foodstuffs (usually tonic waters and energy drinks). Quinine and caffeine must be mentioned in the ingredients list, preceded by the term "flavoring". Beverages containing more than 150 mg of caffeine per liter will have to be labeled with "high caffeine content", followed by the caffeine content expressed in mg/100 ml.

Q. Cocoa

The Ministry Council dated March 12th 2003 has approved the Legal Decree n. 178 that came into force June 12th 2003 and carries out the directive 2000/36/EC. The mentioned decree regulates cocoa and chocolate products destined to human nutrition. It determines that vegetable far other than cocoa butter may be added to cocoa and chocolate products up to a maximum 5% of the finished product and that the other ingredients must not exceed 40%.

SECTION VIII. COPYRIGHT AND/OR TRADEMARK LAWS

Copyrights and trademarks are subject to Italian Royal Decree No 929 dated June 21, 1942 no. 929 as modified by Presidential Decree May 8, 1948 no. 795 and Legal Decree December 4, 1992 no. 480. Italy conformed to EU standards which allow for the registration of patents and trademarks with protection throughout the entire European Union. For more information, please refer to EU FAIRS report E23195.

The authority with jurisdiction over copyright and/or trademark registration is the Italian Trademark and Patent Office in Rome.

Some types of terms may not be registered as trademarks, such as those deemed to be generic, those containing false indications of quality or origin of goods, and terms similar to those already registered by others in Italy (or for which applications are pending.) For some goods, geographic names many not be used in trademarks nor can the portraits of persons be registered without their consent.

Trademark applications are examined for acceptability of their format and consistency with the laws. The first applicant is entitled to registration. If an application is in order, the mark will be registered without opposition. However, any other person who claims to be the first

user of the mark in Italy can have the prior registration cancelled, provided the claim can be proven. No claim of prior use can be made after the registered mark is 5 years old.

Trademarks are registered for 20 years from the effective application filing date and are renewable for similar periods. Failure to use a mark within 3 years after its registration can result in cancellation. Trademarks may be assigned to other users provided such action does not involve deceptive trade practices.

For administrative purposes, trademark products are classified under 42 groups (1-34 for products and 35-42 for services). Applications must indicate the appropriate classification. More information about European trademark law is available at:
http://www.europa.eu.int/scadplus/leg/en/s06020.htm

SECTION IX. IMPORT PROCEDURES

Food products must conform to the regulations required by the Italian and/or EU laws. Products are examined when they enter Italy by inspecting import documents. Tests and relative analysis of samples are performed by health authorities or laboratories. Import operations can be completed and the product may enter commerce within 48 hours from the time of arrival at port if no specific problems arise from the import document inspection or sample testing.

It is important to work with experienced importers, i.e. have agent work with Italian regulatory authorities to ensure acceptability of specific product. It is also advisable for the agent to contact health authorities at port of entry as interpretation of health directives may vary from port to port.

The food divisions undergoing the most strict examinations are of those products of animal derivation (meat in particular), herbalist products and dietary products.

ADVANCE RULINGS FROM ITALIAN CUSTOMS
Prior to signing a long-term contract or sending a shipment of considerable value, it may be prudent for a U.S. exporter or the Italian importer to first obtain an official ruling on the customs classification, duty rate, and taxes that will be applied on the shipment. Such requests should be sent to the Ministry of Finance's Customs Department, Rome, Italy (see Annex A). The request should describe the product, the material it is made from, and other details needed by customs authorities to classify the product correctly. While customs will not provide a binding decision, the advance ruling usually will be accepted if the imported goods are found to correspond exactly to the full description provided when requesting the ruling.

ANNEX A – MAJOR REGULATORY AGENCIES

Ministero delle Politiche Agricole e Forestali
(Ministry of Agriculture)
Via XX Settembre 20
00187 Roma
Tel: +39-06-46651
www.politicheagricole.it

Ministero delle Attivita' Produttive

(Ministry of Productive Activities)
(Bureau of Foreign Trade)
Viale America 341
00144 Roma
Tel 39 06 59931 FAX 39 06 5993 2203/2278
-Dott.ssa Pascarelli tel. 3906 59932175 (Fruits and Vegetables)
-Dott. Perri tel. 3906 5993 2471 (Feed grains)
-D.ssa Campaniello tel. 3906 5993 2204(Meats, Dairy products)
-Dott.ssa Nicosia tel. 3906 5993 2220 (Fats and Oil)

Ministero della Salute
(Ministry of Health)
Direzione Generale per l'Igiene Alimenti e la Nutrizione
Divisione VI . A
Piazza Marconi, Palazzo Italia
00144 Roma
Tel 39-06 5994 Fax 39-065994 3676

National Import Authorities in Ministry of Health:
Ministry of Health
Piazzale Marconi 25
00144 Eur-Rome

Secretariat
Tel 3906-5994-6948 FAX 3906-5994-3190
Dr. Romano Marabelli (General Manager)
for Inspection, Certification, Quarantine, etc.:
Dott. Piergiuseppe Faccelli
Tel. 3906-5994-6613
for Thermal Processed Products:
Dott.ssa Simonetta Bonati (animal products)
Dott.ssa Elvira Cecere (vegetable products)
Food Labeling and Standards:
Dott.ssa Marinella Collauto
For Fishery Products:
Dott. Piergiuseppe Facelli

Ministero delle Finanze
(Ministry of Finance)
Uff. Relazioni Internazionali (International Bureau)
Viale dell`Aeronautica, 122
00144 Roma
Tel. 39 06 5925967 / 54394256
Fax 39 06 5912983
Web site: www.finanze.it

Agenzia delle Dogane
(Customs Agency)
Contact: Mario Andrea Guaiana, Customs Agency Director
Via M. Carucci 71
00143 Roma
Tel.: +39-06-50241
Fax: +39-06-5024-3076
drd.roma.udr@agenziadogane.it
www.agenziadogane.it

Ufficio Centrale Metrico
(Central Metric Office)
Ministry of Productive Activities
Commercio e dell'Artigianato
Direzione Generale per l'armonizzazione e
la Tutela del Mercato
Via Antonio Bosio 15
00161 Roma
Tel 39 -06-8416825 FAX 39-06-8414194

UNI
Ente Nazionale Italiana di Unificazione
(Italian Standards Agency)
Food and Beverage Committee
Via Battistotti Sassi 11-b
20133 Milan
Tel 39 02 700241 FAX 39-02-70106106

ICE
Istituto per il Commercio Estero
(Italian Trade Commission)
Via Liszt, 21
00144 Roma
Tel. 06 59921
www.ice.it

Source of Documents and Publications:
Il Sole 24 Ore Pirola S.P.A.
Via Lomazzo 52
20514 Milano
tel 3902-3022-323

ANNEX B – WTO INFORMATION

The Italian branch of the WTO can be found in the Ministry of Foreign Affairs ("Ministero degli Affari Esteri") at the following address:

Ministero degli Affari Esteri
Piazzale della Farnesino, 1
00194 Roma
Tel: +39 06 36911

ANNEX C –CONTACT INFORMATION FOR OFFICE OF AGRICULTURAL AFFAIRS, ROME

Postal address:
Foreign Agriculture Service
PSC 59 Box 13
APO AE 09624

Street address:
American Embassy
Foreign Agriculture Service
Via Vittorio Veneto 119/A
Rome, 00187
Italy

Telephone:
001 39 06 4674 2396

Fax:
001 39 06 4788 7008

E-mail:
agrome@usda.gov

Minister Counselor for Agricultural Affairs
Geoff Wiggin

Agricultural Attache
Ann Murphy

Agricultural Marketing Specialist
Dana Biasetti